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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,647	02/10/2004	Stephen F. Badylak	3220-74581	1287
7590 Barnes & Thornburg 11 South Meridian Street Indianapolis, IN 46204				
EXAMINER AFREM(OVA, VERA				
ART UNIT		PAPER NUMBER		
1657				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/775,647

## Applicant(s)

BADYLAK ET AL.

## Examiner

Vera Afremova

## Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) 32, 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-31, 33, 34, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date 12/23/08, 12/24/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of the species that is "extracellular matrix comprising submucosa and obtained from a urinary bladder" in the reply filed on 12/19/2008 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 32, 35 and 36 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of "extracellular matrix comprising submucosa and obtained from stomach".

Claims 21-31, 33, 34, 37 and 38 are under examination in the instant office action as solely directed to "extracellular matrix comprising submucosa and obtained from a urinary bladder".

### ***Claim Rejections - 35 USC § 112***

Claims 21-31, 33, 34, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 28 recite "a tissue composition comprising a sterilized extracellular matrix material comprising submucosa **and (?)** obtained from a urinary bladder". This phrase is unclear because it is uncertain what components are linked by "and". Is a submucosa obtained from urinary bladder? Is a whole tissue composition obtained from urinary bladder? Is an extracellular matrix obtained from urinary bladder?

Claims 23 and 30 are uncertain because it is unclear what would be a source of “collagens, glycoproteins, proteoglycans and glycosaminoglycans”. These terms have insufficient antecedent basis in the claims 21 and 28. In alternative, claims 23 and 30 further extend rather than limit the claimed tissue composition(s).

Claims 37 and 38 contain redundant limitations that are recited in claims 29 and 30. In alternative, it is unclear what components of the compositions of claims 29 and 30 would not be sterilized and would not contain “collagens, glycoproteins, proteoglycans and glycosaminoglycans” to provide for proper antecedent basis for same or similar structural elements of claims 37 and 38.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24, 26, 28-31, 33, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer-Rosberg et al. (IDS reference; Scandinavian Journal of Gastroenterology. 1996, Vol. 31, No. 5, pages 434-441).

Claims are directed to a tissue composition comprising a sterilized extracellular matrix comprising submucosa obtained from a urinary bladder of a pig. Some claims are further drawn to the presence of collagens, glycoproteins, proteoglycans and glycosaminoglycans in the composition. Some claims are further drawn to sterilization made with a peracetic acid. Some

claims are further drawn to intended use of the composition based on its capacity to induce remodeling in a host. Some claims are further drawn to forms of the composition including sheet or powder and its packaging.

Meyer-Rosberg et al. discloses a tissue composition for culturing clinical bacterial strains wherein the composition comprises extracellular matrix material such as a biopsy specimen from a urinary bladder of a pig that is separated from muscle layer, thereby, comprising remaining submucosa. The cited material inherently comprises identical generic "collagens, glycoproteins, proteoglycans and glycosaminoglycans" within the meaning of the instant claims for being derived from the same source and composed of the same tissue materials. The cited material is treated with antibiotics prior to inoculation with bacterial strains and, thus, it is a sterilized material before its use. The claimed limitation "peracetic acid" relates to a product-obtained-by-process limitation and it is noted reasonably expected to be a component of the final product that is intended for growing/modifying viable cells but not for killing the viable cells or "host". The form of the cited composition appears to be used in a form of "a native sheet" as encompassed by some of the claims. Thus, the cited reference anticipates the claimed invention.

Claims 21-31, 33, 34, 37 and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by US 5,554,389 or WO 96/31225 (both are IDS references).

Claims are directed to a tissue composition comprising a sterilized extracellular matrix comprising submucosa obtained from a urinary bladder of a pig. Some claims are further drawn to the presence of collagens, glycoproteins, proteoglycans and glycosaminoglycans in the composition. Some claims are further drawn to sterilization made with a peracetic acid. Some

claims are further drawn to intended use of the composition based on its capacity to induce remodeling in a host. Some claims are further drawn to forms of the composition including sheet or powder and its packaging.

US 5,554,389 teaches a tissue composition (entire document) comprising a sterilized extracellular matrix comprising submucosa obtained from a urinary bladder (col.1, line 66) of a pig (col. 2, line 12). The cited material inherently comprises identical generic "collagens, glycoproteins, proteoglycans and glycosaminoglycans" within the meaning of the instant claims for being derived from the same source and composed of the same tissue materials. The cited material is sterilized with a peracetic acid (col. 5, line 3). The cited material is intended as graft and thus, has capacity to induce remodeling in a host. The cited material is in a form of native sheet (col.3, line 19) or powder (col. 2, line 50) and packaged in plastic wrap (col. 5, line 17). Thus, the cited reference US 5,554,389 anticipates the claimed invention.

The documents US 5,554,389 and WO 96/31225 have identical disclosure. Thus, the cited reference WO 96/31225 also anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-31, 33, 34, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Rosberg et al. (Scandinavian Journal of Gastroenterology. 1996, Vol. 31, No. 5, pages 434-441), US 5,554,389 and WO 96/31225.

Claims are directed to a tissue composition comprising a sterilized extracellular matrix comprising submucosa obtained from a urinary bladder of a pig. Some claims are further drawn to the presence of collagens, glycoproteins, proteoglycans and glycosaminoglycans in the composition. Some claims are further drawn to sterilization made with a peracetic acid. Some claims are further drawn to intended use of the composition based on its capacity to induce remodeling in a host. Some claims are further drawn to forms of the composition including sheet or powder and its packaging.

All cited references Meyer-Rosberg et al., US 5,554,389 and WO 96/31225 teach tissue compositions with a sterilized extracellular matrix comprising submucosa obtained from a urinary bladder of a pig. The cited compositions are intended for cell culturing and/or for tissue grafts. The composition of Meyer-Rosberg et al. is described as being in a form a sheet. But the cited US 5,554,389 and WO 96/31225 teach that the same materials are made in both forms including sheets and powders and that they are packaged in plastic wraps.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to provide submucosa materials obtained from a urinary bladder of a pig in various forms including sheets and powders and in variety of packaging including plastic wraps with a reasonable expectation of success in applications related to cell culturing and/or for tissue grafts. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to

patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 21-31, 33, 34, 37 and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. US 6,187,039.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to a tissue composition comprising a sterilized extracellular matrix comprising submucosa obtained from warm-blooded vertebrate animals. The pending claims are broader since they are directed to a generic product suitable for cell culturing and grafting. The issued claims are narrower since they define a multi-layered product intended for



grating as well as suitable for cell culturing. The pending claims are narrower since they are limited to the use of a pig derived submucosa. The issued claims are broader since they directed to the use of submucosa obtained from warm-blooded vertebrate animals (claim 9, for example) including pigs in view of specification (col. 3, line 1, for example).

Accordingly, the claimed products in the issued patent and in the present application are obvious variants. Therefore, the inventions as claimed are co-extensive.

2. Claims 21-31, 33, 34, 37 and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-20 and 25-27 of U.S. Patent No. US 6,375,989 (Badylak et al.)

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to a tissue composition or tissue extract comprising a components derived from submucosa of vertebrate animals including extracellular matrix, proteins, glycosamines, etc. The pending claims are narrower since they are limited to the use of a pig derived submucosa. The issued claims are broader since they directed to the use of submucosa obtained from warm-blooded vertebrate animals including pigs in view of specification (abstract and col. 2, line 7). The pending claims are narrower since they are limited to the use of a urinary bladder. The issued claims are broader since they directed to the use of submucosa obtained from various animal parts including urinary bladder in view of specification (col. 21, line 9, for example).

Accordingly, the claimed products in the issued patent and in the present application are obvious variants. Therefore, the inventions as claimed are co-extensive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

January 12, 2009

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/  
Primary Examiner, Art Unit 1657